UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

In re: CELEXA AND LEXAPRO MARKETING AND SALES PRACTICES LITIGATION THIS DOCUMENT RELATES TO: LOCONTE, ET AL.	MDL No. 2067 Master Docket No. 09–MD–2067 Judge Nathaniel M. Gorton 14–CV–13848 (NMG)

MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS THE *LOCONTE* COMPLAINT

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Forest Laboratories, LLC (successor in interest to Forest Laboratories, Inc.) and Forest Pharmaceuticals, Inc. ("Forest" or "Defendants"), move to dismiss the Complaint for failure to state a claim, Fed. R. Civ. P. 12(b)(6), and failure to plead fraud with particularity. *Id.* 9(b).[1]

I. PRELIMINARY STATEMENT

The Complaint is yet another attempt by Plaintiffs' counsel to find a claim. Premised on the same allegations relating to pediatric use of Celexa and Lexapro asserted in multiple complaints over nearly five years, counsel this time packages the claims of two consumers into a new action seeking to certify a nationwide RICO class and state-wide classes in Massachusetts and Washington. The Complaint should be dismissed for multiple reasons.

First, all claims are untimely based on this Court's recent decision in the *Painters* and *Allied Services* actions ("***Painters* Order**").[2] Plaintiffs' claims are subject to four-year and three-year statutes of limitations ("SOL"). This Court held that virtually identical claims asserted by the *Painters* and *Allied Services* plaintiffs "accrued no later than March 2009."[3] The present Complaint was filed in August 2014, over ***five years*** later, and no tolling can save the claims.

Second, the Complaint fails to plead a cognizable RICO injury. Plaintiffs are consumers who purchased Celexa or Lexapro for their minor children. Rather than expressly alleging the drugs were ineffective or unsafe for their children (because doing so would aggravate their SOL defects and create individualized issues), Plaintiffs appear to allege only that they were deprived of "informed choice." Plaintiffs' "novel" claim for relief—as this Court termed the "informed

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1 A copy of the Complaint ("Compl.") is attached as Exhibit 1 to the Declaration of J. Robert Abraham in Support of Defendants' Motion to Dismiss the *LoConte* Complaint ("Abraham Decl.").

2 Memorandum & Order, *In re Celexa & Lexapro Mktg. & Sales Practices Litig.*, No. 09–MD–2067 (NMG) (D. Mass. Dec. 12, 2014) (DE 465).

3 *Id.* at 10.

choice" theory advanced by Plaintiffs' counsel in other actions[4]—is not remotely "definite" or "measurable" as required to sustain a RICO claim.

Third, the Complaint fails to state a claim for relief under the consumer protection laws of Washington or Massachusetts. Plaintiffs' "informed choice" theory of injury is not recognized by either state. The Complaint also fails to plausibly allege causation under either state's law, and fails to state a claim for unjust enrichment.

For all the reasons discussed herein, the Complaint should be dismissed with prejudice.

II. STATEMENT OF FACTS AND ALLEGATIONS[5]

A. BACKGROUND

The allegations are familiar to the Court. Celexa and Lexapro are prescription antidepressants sold by Forest. Compl. ¶¶ 11, 20. Both belong to a class of antidepressants known as selective serotonin reuptake inhibitors ("SSRIs"). *Id.* ¶ 20. Celexa is approved by the U.S. Food and Drug Administration ("FDA") for the treatment of depression in patients aged 18 years and older. *Id.* ¶ 36. Lexapro is approved by the FDA for the treatment of depression in adolescents aged 12–17 years and in adults aged 18 years and older. *Id.* ¶¶ 57, 67.

Two pediatric clinical studies of Celexa were unblinded in 2001 and submitted to the FDA in 2002. *Id.* ¶¶ 40, 52. The FDA determined that one study, MD–18, is a positive study supporting the conclusion that Celexa is effective in treating pediatric depression, *id.* ¶¶ 52, 67, whereas the second study is a negative study that does not support efficacy in pediatric patients

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[4] Memorandum & Order at 16, *In re Celexa & Lexapro Mktg. & Sales Practices Litig.*, 09–MD–2067 (NMG) (D. Mass. Jan. 10, 2014) (DE 312) ("***Jaeckel*/*Palumbo* Class Cert Decision**").

[5] The complaint's well-pleaded factual allegations are accepted as true solely for purposes of this motion, except to the extent they are contradicted by documents cited in the complaint. *See Clorox Co. P.R. v. Proctor & Gamble Commercial Co.*, 228 F.3d 24, 32 (1st Cir. 2000).

("Lundbeck Study").[6] *Id.* ¶ 54. As a result, in 2003, the FDA concluded there was insufficient evidence of efficacy to warrant a pediatric indication for Celexa. *Id.*

Until early 2005, the FDA-approved labels for both drugs stated that "Safety and effectiveness in pediatric patients have not been established."[7] In early 2005, Celexa's label was supplemented with a description of the Lundbeck Study. *Id.* ¶ 185. At the same time, Lexapro's label was supplemented with a description of a negative Lexapro pediatric study completed in 2004. *Id.* ¶ 191. Both labels also added a supplemental statement indicating that clinical data were not sufficient to support an indication for use in pediatric patients. *Id*. ¶ 185; s*ee also* Kasten Decl. Ex. 66 (February 2005 Celexa Label); *id.* Ex. 67 (February 2005 Lexapro Label)..

In March 2009, the FDA approved Lexapro as safe and effective for adolescent depression based in part on the MD–18 Celexa study and in part on a positive study of Lexapro in adolescents completed in 2007 (MD–32). *Id.* ¶¶ 66–67. Lexapro's label was revised to reflect the FDA's conclusion that Lexapro is safe and effective for adolescents. *Id.* ¶ 192.

B. PLAINTIFFS' CLAIMS

Plaintiffs are consumers whose minor children were prescribed Celexa or Lexapro. *Id.* ¶¶ 198, 213. Plaintiff LoConte paid for Lexapro prescriptions for her son for a period of several years, from November 2004, when he was 14 years of age, until at least 2010. *Id.* ¶¶ 198, 202. Plaintiff Kiossovksi paid for Celexa prescriptions for her daughter for approximately eight months, from July 2001, when her daughter was 12 years of age, until March 2002. *Id.* ¶ 213.

Plaintiffs allege in blanket fashion that clinical data have shown the drugs "do not

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[6] A negative study does not prove that a drug lacks efficacy, but rather fails to support the conclusion that the drug is more effective than a placebo in that study. *See Smith v. Wyeth-Ayerst Labs. Co.*, 278 F. Supp. 2d 684, 693 n.14 (W.D.N.C. 2003).

[7] *See* Declaration of Danielle E. Kasten in Support of Defendants' Request for Judicial Notice ("Kasten Decl.") Ex. 64 (July 1998 Celexa label); *id*. Ex. 65 (Aug. 2002 Lexapro label). As explained in Defendants' Request for Judicial Notice, the Court may take judicial notice of these and all other exhibits to the Kasten Declaration.

provide a clinically significant benefit over placebo" in treating pediatric depression. *Id.* ¶ 2. However, neither Plaintiff alleges that the drugs she purchased were ineffective or unsafe for her own child. To the contrary, Plaintiffs allege that "Nothing in the course of [their] child's treatment provided [Plaintiffs] any impetus to suspect Forest's . . . foul play." *Id.* ¶¶ 208; 222. Instead, Plaintiffs apparently seek to recover for a deprivation of "material information . . . needed to make an informed decision" about whether to purchase the drugs, which deprivation purportedly led them to make payments they would not otherwise have made. *Id*. ¶¶ 200; 215.

Plaintiffs bring claims under (***i***) the Racketeer Influenced and Corrupt Organizations Act ("RICO"), 18 U.S.C. §§ 1961 *et seq.* (Counts I–II); (***ii***) Chapter 93A of the General Laws of Massachusetts ("Chapter 93A"), Mass. Gen. L. Ch. 93A (Count III); (***iii***) the Washington Consumer Protection Act ("WCPA"), Wash. Rev. Code §§ 19.86 *et seq.* (Count IV); and (***iv***) the common law for unjust enrichment (Count V).

C. PROCEDURAL HISTORY

On February 25, 2009, a complaint against Forest filed by the United States was unsealed, alleging that Forest had promoted Celexa and Lexapro for off-label pediatric use and suppressed the Lundbeck Study ("***Qui Tam* Complaint**").[8] Soon thereafter, a number of civil complaints were filed on behalf of putative classes of consumers and third-party payors ("TPPs") based on the same allegations in the *Qui Tam* Complaint, leading to the creation of this Multi-District Litigation ("**MDL**"). Plaintiffs' counsel have been active participants in the MDL:

March 2009 — A complaint was filed on behalf of a nationwide class of TPPs, asserting RICO and consumer fraud claims based on the allegations in the Qui Tam Complaint ("**March 2009 RICO Action**").[9]

[8] *See* Kasten Decl. Ex. 59 (*U.S.* Complaint in Intervention).

[9] Kasten Decl. Ex. 60 (*New Mexico UFCW* Complaint). The complaint was voluntarily dismissed in June 2010.

March 2009 Plaintiffs' counsel filed the *Jaeckel* complaint, asserting consumer fraud claims on behalf of a nationwide consumer class based on the allegations in the Qui Tam Complaint ("**Jaeckel Action**").[10]

June 9, 2009 A complaint was filed on behalf of a nationwide consumer class, asserting RICO and consumer fraud claims based on the allegations in the Qui Tam Complaint ("***Anson* Consumer/RICO Action**").[11]

July 2009 Plaintiffs' counsel filed the *Palumbo* complaint, asserting consumer fraud claims on behalf of a nationwide consumer class based on the allegations in the Qui Tam Complaint.[12]

February 2013 This Court denied the *Jaeckel* and *Palumbo* plaintiffs' motions to certify a nationwide class. The Court also denied a consumer's motion to certify a California class in the *Wilcox* action.[13]

April 2013 Plaintiffs' counsel filed an amended complaint in the *Jaeckel*/*Palumbo* actions, asserting consumer fraud claims based on the same allegations in the prior complaints, but this time seeking to certify state-wide classes in Illinois, New York, and Missouri based on a new theory of injury designed to avoid the fate of the *Wilcox* action—*i.e.*, plaintiffs alleged they were denied the opportunity to make an informed choice about whether to purchase Celexa or Lexapro.[14]

May 2013 Plaintiffs' counsel filed the *Marcus* action, asserting consumer fraud claims on behalf of a California class based on a theory that Lexapro's current label is false and misleading.[15]

January 2014 This Court denied the *Jaeckel*/*Palumbo* plaintiffs' motion to certify Illinois and New York classes, finding that the "informed choice" theory was not cognizable under either State's law.[16]

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[10] Class Action Complaint, *Jaeckel, et al. v. Forest Pharm., Inc., et al.*, No. 09–CV–11518 (NMG) (D. Mass. Mar. 20, 2009) (DE 1).

[11] *See id*. Ex. 62 (*Anson* Complaint). The complaint was voluntarily dismissed in March 2010.

[12] Class Action Complaint, *Palumbo, et al. v. Forest Labs., Inc., et al.*, No. 09–CV–11532 (NMG) (D. Mass. July 6, 2009) (DE 2).

[13] Memorandum & Order, *In re Celexa & Lexapro Mktg. & Sales Practices Litig.*, No. 09–MD–2067 (NMG) (D. Mass. Feb. 5, 2013) (DE 174).

[14] Second Amended Complaint, *Jaeckel, et al. v. Forest Pharmaceuticals, et al.*, No. 09–MD–2067 (NMG)) (DE 213).

[15] Complaint, *Marcus v. Forest Pharm., Inc., et al.*, No. 13–CV–11343 (D. Mass. May 3, 2013 (DE 1). This Court dismissed the complaint in March 2014.

[16] *Jaeckel*/*Palumbo* Class Cert Decision at 19–22. The Court certified a Missouri class.

November 2013 Still seeking to certify a nationwide class, Plaintiffs' counsel filed a new complaint on behalf of a nationwide class of TPPs ("***Painters* Action**")[17] based on the same allegations as the *Jaeckel*/*Palumbo* complaints, but substituting RICO claims for consumer fraud claims.

August 28, 2014 Plaintiffs' counsel filed the present Complaint on behalf of a nationwide consumer class, asserting the same allegations and RICO claims as the *Painters* and *Allied Services* actions, as well as consumer fraud claims on behalf of Massachusetts and Washington consumers and TPPs.

III. ARGUMENT

The Complaint should be dismissed in its entirety because the claims are time-barred. The Complaint also fails to state a claim for relief that is "plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). A plaintiff must plead facts that "raise a right to relief above the speculative level." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007). "Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Iqbal*, 556 U.S. at 678. Because the Complaint is based on allegations of fraud, Plaintiffs must plead their claims with particularity under Federal Rule of Civil Procedure 9(b).

A. ALL CLAIMS ARE BARRED BY THE STATUTES OF LIMITATIONS.

1. The RICO Claims Are Time-Barred

The SOL for civil RICO claims is four years after a plaintiff discovers or should have discovered her injury. *See Rotella v. Wood*, 528 U.S. 549, 552–55 (2000). A plaintiff should have discovered her injury when a diligent plaintiff would have done so. *See Klehr v. A.O. Smith Corp.*, 521 U.S. 179, 187 (1997). RICO plaintiffs are required to "diligently" investigate potential claims—they may not simply stand idly by and assert claims many years later claiming they had no reason to know of their injury. *See id.; see also Jay E. Hayden Found. v. First Neighbor Bank, N.A.*, 610 F.3d 382, 385–86 (7th Cir. 2010) (Posner, J.) (holding RICO SOL starts running when plaintiff discovers or "should if diligent have discovered" injury; "plaintiff

[17] *See* Kasten Decl. Ex. 63 (*Painters* Complaint).

cannot fold his hands, sit back, and do nothing," but must "continue investigating diligently"). Whether a diligent plaintiff should have discovered the injury, *i.e.* was on inquiry notice, "need not be left to a finder of fact" and may be determined as a matter of law. *In re Merrill Lynch Ltd. P'ships Litig.*, 154 F.3d 56, 60 (2d Cir. 1998); *see also Cabrera v. Countrywide Fin.*, No. C 11-4869 SI, 2012 WL 5372116, at *3 (N.D. Cal. Oct. 30, 2012) (dismissing untimely RICO claims where "reasonably diligent investigation of the loan documents" available to plaintiff would have revealed injury).

The Complaint was filed on August 28, 2014. Thus, if Plaintiffs knew or should have known of their alleged injuries before August 28, 2010, the RICO claims are time-barred.

a. *Plaintiffs' Claims Are Untimely Because This Court Has Already Ruled That Virtually Identical Claims Accrued No Later Than March 2009*

Plaintiffs vaguely assert they were unaware they were victims of Forest's alleged fraud until "sometime after November 2013" (Plaintiff LoConte) or "until January 2014" (Plaintiff Kiossovski). Compl. ¶¶ 210, 224. In determining the SOL for RICO claims, the relevant question is when a diligent plaintiff would have discovered the injury. The complaints filed in March and June 2009 asserting largely identical claims and allegations establish that a diligent plaintiff would have discovered her alleged injury by then, at the very latest.

In the *Allied Services* and *Painters* actions, this Court concluded that "the undisputed facts support a finding that the SOL for plaintiff's RICO claims accrued no later than March, 2009, when the national RICO class action was filed following the unsealing of the government's *qui tam* complaint against Forest alleging off-label pediatric promotion and concealment of the Lundbeck study." *Painters* Order at 10; *see also Sidney Hillman Health Ctr. v. Abbott Labs.*, No. 13 C 5865, 2014 WL 4057439, at *5 (N.D. Ill. Aug. 14, 2014) (dismissing RICO claims where injury was clearly discoverable following company's disclosure that it was

under government investigation and subsequent unsealing of *qui tam* complaints). Plaintiffs' claims are virtually identical to the claims and allegations asserted in the *Painters* and *Allied Services* complaints. Therefore, this Court's prior finding is equally applicable to the present Complaint. The SOL for Plaintiffs' RICO claims accrued no later than March 2009 and expired in March 2013, ***17 months before*** the Complaint was filed.

The filing of the *Anson* Consumer/RICO Action in June 2009 provides further support for the conclusion that a reasonably diligent plaintiff was on notice of her alleged injury. That lawsuit asserted RICO claims on behalf of a putative nationwide class of consumers based on the same allegations in the Qui Tam Complaint. As such, even if the SOL for Plaintiffs' RICO claims had not already accrued in March 2009, it indisputably accrued in June 2009 and expired in June 2013—***14 months*** before the Complaint was filed.

b. *Plaintiffs' Alleged Injury Was Apparent Long Before March 2009*

Although the Court's prior ruling on accrual renders the claims time-barred, Plaintiffs' claims actually accrued well before March 2009. The admissions in the Complaint and the abundance of information in the public domain—coupled with a RICO plaintiff's duty to diligently investigate its claims—confirms that relevant information was available and that a diligent plaintiff would have discovered the alleged injury before then.

Information in the public domain included:

- The statement appearing in Celexa's label beginning in 1998: "**Efficacy in pediatric patients has not been established**."[18]
- The statement appearing in Lexapro's label beginning in 2001: "**Efficacy in pediatric patients has not been established**."[19]
- Publication on June 21, 2004 of a *New York Times* article alleging Forest had concealed the Lundbeck Study.[20]

[18] Kasten Decl. Ex. 64 (July 1998 Celexa Label), at 11.

[19] *Id.* Ex. 65 (August 2002 Lexapro Label), at 12.

- Forest's issuance on June 24, 2004 of two press releases—one announcing the results of the Lundbeck Study[21] and the other announcing a negative Lexapro pediatric study.[22]
- Publication on June 26, 2004 of a *New York Times* article discussing Forest's public announcement of the negative studies.[23]
- Publication on June 30, 2004 of a *New York Times* article recapping these events and noting Forest had received an inquiry from the N.Y. Attorney General ("NYAG").[24]
- Forest's issuance on September 7, 2004 of a press release announcing that Forest had resolved the NYAG inquiry and agreed to post all study results on an online clinical trial registry.[25]
- Forest's issuance on February 8, 2005 of a press release announcing the launch of a website containing the results of all pediatric Lexapro and Celexa studies.[26]
- Supplemental content added to Celexa's label in early 2005: "**Two placebo-controlled trials in 407 pediatric patients with MDD have been conducted with Celexa, and the data were not sufficient to support a claim for use in pediatric patients**."[27]
- Supplemental content added to Lexapro's label in early 2005: "**One placebo-controlled trial in 264 pediatric patients with MDD has been conducted with Lexapro, and the data were not sufficient to support a claim for use in pediatric patients**."[28]

Given that both drugs' labels plainly stated "**Efficacy in pediatric patients has not been established**," Plaintiffs' assertion that "there was no publicly available reason to think [the drugs] would be clinically ineffective" is absurd. Compl. ¶ 176. Even Plaintiffs assert that drug labels "serve as the primary authority for understanding the . . . proposed benefit of a drug" and are "the single most important source of information . . . ." *Id.* ¶ 179. Furthermore, by February 2005, there was no "concealment" of negative studies or potential safety issues. Not only were

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20 Kasten Decl. Ex. 33 (*NYT* article, June 21, 2004).

21 *Id.* Ex. 52 (Celexa Press Release, June 24, 2004).

22 *Id.* Ex. 53 (Lexapro Press Release, June 24, 2004).

23 *Id.* Ex. 36 (*NYT* article, June 26, 2004).

24 *See id.* Ex. 37 (*NYT* article, June 30, 2004).

25 *See id.* Ex. 54 (Press Release, Sept. 7, 2004).

26 *See id.* Ex. 56 (Press Release, Feb. 8, 2005).

27 Compl. ¶ 185; *see also* Kasten Decl. Ex. 66 (February 2005 Celexa Label), at 2.

28 Kasten Decl. Ex. 67 (February 2005 Lexapro Label), at 2.

the negative studies and a black-box safety warning added to the labels,[29] but Forest itself publicly announced the negative studies in press releases in June 2004, and information about the studies was widely publicized and available to physicians and the public in the press and online.

Press coverage was widespread. There was consistent public debate over the clinical benefit of Celexa, Lexapro, and other SSRIs for the treatment of pediatric depression, as well as the "placebo effect" and the potential for suicidality (which Plaintiffs describe as an "avalanche of controversy," Compl. ¶ 188 n.15), throughout the relevant time period and dating as far back as 1999.[30] Defendants' Request for Judicial Notice, filed concurrently with this Motion to Dismiss, identifies dozens of print articles from across the country, which represent just a sample of this public discourse. Plaintiffs' own Complaint identifies several such publications. The availability of these publications, combined with Forest's own announcements *and* the supplemental content added to the labels, "clearly show that a reasonably diligent consumer could have discovered information regarding the placebo effect, [the drugs' alleged lack of] effectiveness, and unpublished clinical trials." *Plumlee v. Pfizer, Inc.*, No. 13–CV–414–LHK, 2014 WL 4275519, at *8–9 (N.D. Cal. Aug. 29, 2014) (dismissing similar complaint filed by Zoloft consumer). Indeed, numerous plaintiffs had done so by March and June 2009.

Finally, Plaintiff Kiossovski pleads facts suggesting she personally was on notice as far back as March 2002. She alleges that, after taking Celexa, her daughter's depression worsened and she was admitted to the hospital in or around March 2002. Compl. ¶ 213. In *Plumlee v. Pfizer*, a California district court dismissed a similar complaint filed by Plaintiffs' counsel on behalf of a consumer of the SSRI Zoloft. 2014 WL 4275519. There, the plaintiff alleged that

[29] Although Plaintiffs suggest that the supplemental information added to the drug labels was not sufficiently fulsome, the information unquestionably was sufficient to put a reasonably diligent plaintiff on notice of the existence of negative studies and the potential for suicidality.

[30] Indeed, Plaintiffs concede that the "placebo effect," and its ability to "undermine[]" clinical trial results, has been widely recognized ***since 1955***. *See* Compl. ¶ 28 & n.1.

Pfizer marketed Zoloft as an effective treatment for depression, while concealing clinical studies allegedly showing the drug is no better than a placebo. *Id*. at *1–2. The *Plumlee* court dismissed the claims as time-barred under California law: "What is noticeably absent from the FAC is any allegation that Plaintiff took any steps to discover why Zoloft was ineffective in treating her depression between June 2008 . . . and May 2012 . . . . [O]nce she knew Zoloft was ineffective for her, she could not 'wait for [the facts] to find [her] and sit on [her] rights,' rather she had to 'go find' the available facts." *Id*. at *7. Similarly, Plaintiff Kiossovski does not allege that she took any steps during the ensuing 14 years to discover why Celexa might have been ineffective in treating her daughter's depression.

c. *The RICO Claims Cannot Be Tolled*.

The RICO claims cannot be saved by *American Pipe* tolling. *First*, this Court has already ruled that the *Jaeckel* Action does not toll RICO claims. *Painters* Order at 14. *Second*, the only RICO action that could have included Plaintiffs as class members was the *Anson* Consumer/RICO Action, which was filed in June 2009 and voluntarily dismissed in March 2010. Even assuming a voluntarily dismissed class action can toll claims, the *Anson* Consumer/RICO Action would have tolled the SOL for only nine months and thus would not save these claims.[31]

2. <u>The State Law Claims Are Time-Barred</u>

Plaintiffs' individual state law claims (Counts III, IV, and VI) are also time-barred.[32]

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[31] Similarly, even if the March 2009 RICO Complaint tolled the SOL (which it did not because Plaintiffs are not "entities" within that complaint's class definition), it would toll the SOL for only 15 months and likewise would not save Plaintiffs' claims.

[32] Like the RICO claims, Plaintiffs' state law claims cannot be saved by *American Pipe* tolling. None of the previous class actions sought to certify a consumer class under the laws of Washington or Massachusetts, and neither state has recognized cross-jurisdictional tolling (*i.e.* tolling of state law claims based on a class action pending in federal court or in another state). *See, e.g., Patterson v. Norvartis Pharm. Corp.*, 909 F. Supp. 2d 116, 122–23 (D.R.I. 2012) (refusing to apply cross jurisdictional class action tolling to Massachusetts state law claims).

a. *The Massachusetts State Law Claims Are Time-Barred*

Plaintiff LoConte's consumer protection claim under Chapter 93A is governed by a four-year SOL. *See* Mass. Gen. L. ch. 260, § 5A. Her unjust enrichment claim is governed by a three-year SOL. *See Figueroa v. Bank of Am., N.A.*, No. 12–11290, 2012 WL 5921043, at *4 (D. Mass. Nov. 26, 2012). Under the discovery rule, each claim accrues "when the plaintiff knew or should have known of appreciable harm resulting from the defendant's [actions]." *Schwartz v. Travelers Indem. Co.*, 740 N.E.2d 1039, 1044 (Mass. App. Ct. 2001) (citations omitted); *see also Abdallah v. Bain Capital LLC*, 880 F. Supp. 2d 190, 195–96 (D. Mass. 2012), *aff'd*, 752 F.3d 114 (1st Cir. 2014). Similar to the RICO claims, Plaintiff's claims are untimely if she knew or should have known of injury resulting from Forest's alleged acts before August 28, 2010 (Chapter 93A claim) or August 28, 2011 (unjust enrichment claim). For the reasons discussed above, Plaintiff's claims are untimely because they accrued no later than March 2009.

Plaintiff unsuccessfully attempts to allege a basis for the delayed discovery rule or the doctrine of fraudulent concealment. To benefit from those doctrines, Plaintiff must establish that "a plaintiff exercising reasonable diligence could not have discovered information essential to the suit." *Abdallah v. Bain Capital LLC*, 752 F.3d 114, 119–20 (1st Cir. 2014). Plaintiff does not allege any facts to establish that she exercised reasonable diligence. Instead, she claims that during the course of her son's treatment, she "did not have any reason to investigate"; was "never informed" about negative studies; "did not see any media, journal articles, press releases, [or] websites" about lack of clinical significance; and "had no reason to believe" she was the victim of a consumer protection violation. Compl. ¶¶ 204–06, 210. However, a plaintiff exercising reasonable diligence indisputably could have discovered information essential to her suit by March 2009, and certainly by June 2009. Plaintiff does not offer any explanation for why other plaintiffs were able to discover their injuries, but Plaintiff remained in the dark until

November 2013. *See, e.g.*, *Sidney Hillman*, 2014 WL 4057439, at *7 (dismissing untimely unjust enrichment claims); *Ford v. Lehman Capital*, No. 10–40092–FDS, 2012 WL 1343977 (D. Mass. Apr. 17, 2012) (dismissing untimely Chapter 93A claim where documents in plaintiffs' possession put her on notice of claim).[33]

b. *The Washington State Law Claims Are Time-Barred*

Plaintiff Kiossovski's WCPA claim must be brought within four years of accrual, Wash. Rev. Code § 19.86.120, and her unjust enrichment claim must be brought within three years of accrual. *Id*. § 4.16.080(3); *see also Cain v. Source One Mortg. Servs. Corp.*, No. 43041–6–I, 1999 Wash. App. LEXIS 1600, at *3 (Wash. Ct. App. Aug. 30, 1999). In both cases, where the allegations relate to fraud, a claim accrues when the plaintiff knew or should have known of the relevant facts, whether or not she knew the facts were sufficient to establish a cause of action. *Cain*, 1999 Wash. App. LEXIS 1600, at *3. Thus, similar to the RICO claims, Plaintiff's state law claims are time-barred if she knew or should have known of the relevant facts before August 28, 2010 (WCPA claim) or August 28, 2011 (unjust enrichment claim).

Again, the filing of the March and June 2009 complaints demonstrates that the relevant facts—including the existence of negative studies and Forest's alleged off-label promotion of Celexa for pediatric use—were publicly available and ascertainable by a reasonably diligent plaintiff.[34] *See, e.g.*, *Stephenson v. First Am. Title Ins. Co.*, No. C13–1150 RSM, 2014 WL 2894692, at *3 (W.D. Wash. June 25, 2014) (dismissing WCPA claims where plaintiff "knew or should have known" relevant facts before expiration of SOL); *Pruss v. Bank of Am. NA*, No.

[33] *See also Bernier v. Upjohn Co.*, 144 F.3d 178, 180 (1st Cir. 1998) (rejecting equitable tolling under Massachusetts law where plaintiff failed to establish that document critical to her claims could not have been discovered earlier through "reasonable diligence").

[34] Furthermore, Plaintiff concedes in the Complaint that she was on notice of relevant facts as far back as March 2002, when her daughter's depression worsened. Compl. ¶ 212; *see also Plumlee*, 2014 WL 4275519, at *7.

C13-1447 MJP, 2013 WL 5913431, at *2–3, *6 (W.D. Wash. Nov. 1, 2013) (dismissing WCPA claim where Plaintiff could have discovered relevant facts with reasonable diligence); *Westcott v. Wells Fargo Bank, N.A.*, 862 F. Supp. 2d 1111, 1115–16, 1118 (W.D. Wash. 2012) (dismissing WCPA claim where plaintiffs offered no reason why they could not have timely discovered basis for claim); *Lowden v. T-Mobile USA, Inc.*, No. C05–1482 MJP, 2009 WL 537787, at *4 (W.D. Wash. Feb. 18, 2009), *aff'd*, 378 F. App'x 693 (9th Cir. 2010) (dismissing unjust enrichment claim where plaintiff brought suit several years after payment to defendant).

Similar to Plaintiff LoConte, Plaintiff Kiossovski unsuccessfully attempts to allege a basis for the delayed discovery rule or the doctrine of fraudulent concealment. To benefit from these doctrines, Plaintiff "must show there were impediments to earlier prosecution of the claim, including the reasons [she] did not know of the cause of action, the means used to keep [her] ignorant, and how [s]he first obtained knowledge of the relevant facts." *Pruss*, 2013 WL 5913431, at *3 (citing *Douglass v. Stanger*, 2 P.3d 998 (Wash. Ct. App. 2000)). Although Plaintiff alleges *when* she learned of her claims, Compl. ¶ 224, she fails to articulate *what* occurred in January 2014 to enable her to "discover" her claim at that time, or why she could not have discovered the relevant facts between March 2009—when other diligent plaintiffs did so—and January 2014.

B. THE RICO CLAIMS FAIL BECAUSE THE COMPLAINT FAILS TO ALLEGE AN INJURY.

The Complaint should also be dismissed because it fails to plead a cognizable RICO injury. *See Sedima, S.P.R.L. v. Imrex Co.*, 473 U.S. 479, 496 (1985).

To satisfy RICO's standing criteria, the Complaint must allege an injury to Plaintiffs' business or property by reason of a violation of Section 1962. *See First Nationwide Bank v. Gelt Funding Corp.*, 27 F.3d 763, 767 (2d Cir. 1994). A plaintiff may not simply plead "any theory of injury." *In re Schering-Plough Corp. Intron/Temodar Consumer Class Action*, No. 2:06–cv–

5774 (SRC), 2009 WL 2043604, at *11 (D.N.J. July 10, 2009); *see also DeMauro v. DeMauro*, 115 F.3d 94, 97 (1st Cir. 1997) (noting "injury to property" is "not an infinitely elastic concept"). Rather, the alleged injury must be a definite and measurable injury that is neither hypothetical nor speculative. *See, e.g., First Nationwide*, 27 F.3d at 768; *Circiello v. Alfano*, 612 F. Supp. 2d 111, 114 (D. Mass. 2009). The reason for this restriction is to ensure that "RICO is not expanded to provide a federal cause of action and treble damages to every tort plaintiff." *Maio v. Aetna, Inc.*, 221 F.3d 472, 483 (3d Cir. 2000) (internal quotation marks omitted).

Plaintiffs' "novel" claim for relief is that they paid for drugs while being "deprived . . . of material information." Compl. ¶¶ 200, 215. Plaintiffs do not allege that the drugs they purchased were ineffective, unsafe, or otherwise harmed their children.[35] Indeed, both Plaintiffs claim that "nothing in the course of [their] [children's] treatment gave [them] any impetus" to suspect Forest had suppressed negative efficacy information. *Id.* ¶¶ 206, 208, 220, 222.

A deprivation of information, absent an allegation that the product was defective, is precisely the type of "hypothetical" and "speculative" injury for which the RICO statute affords no relief. The information allegedly withheld from Plaintiffs was that the drugs are not clinically effective; yet if the drugs treated their children's depression, then the alleged deprivation of information is irrelevant and Plaintiffs suffered no tangible harm to their business or property. For this reason, federal courts nationwide have rejected RICO claims alleging hypothetical and speculative losses that lack any tangible harm to the plaintiff. *See, e.g.*, *Gotlin v. Lederman*, 483 Fed. App'x 583, 586 (2d Cir. 2012) (no RICO claim for monetary losses "incidental to [plaintiffs'] personal injuries"); *Laborers Local 17 Health and Benefit Fund v. Philip Morris, Inc.*, 191 F.3d 229, 241 (2d Cir. 1999) (no RICO claim for "injuries [that] are personal in

[35] Plaintiff LoConte's son continued to take Lexapro for over five years. *Id.* ¶¶ 198, 202. Although Plaintiff Kiossovski states that her daughter's depression worsened while taking Celexa, *id.* ¶ 213, she too asserts solely an "informed choice" theory of injury. *Id.* ¶¶ 214–15, 273, 318.

nature"); *Hamm v. Rhone-Poulenc Rorer Pharm., Inc.*, 187 F.3d 941, 954 (8th Cir. 1999) (no RICO claim for "damage to reputation"); *In re Taxable Mun. Bond. Sec. Litig.*, 51 F.3d 518, 523 (5th Cir. 1995) (no RICO injury for "lost opportunity to borrow" at low interest rate); *Steele v. Hospital Corp. of Am.*, 36 F.3d 69, 70–71 (9th Cir. 1994) (no RICO injury where plaintiff could have exhausted insurance benefits, but didn't); *Lincoln House, Inc. v. Dupre*, 903 F.2d 845, 847 (1st Cir. 1990) (no RICO injury for "hypothetical inability to recover" assets).

The mere fact that Plaintiffs purchased the drugs does not establish a tangible loss sufficient to plead RICO injury. For example, in *In re Bridgestone/Firestone, Inc. Tires Product Liability Litigation*, 155 F. Supp. 2d 1069 (S.D. Ind. 2001), the plaintiffs alleged they purchased vehicles with defective tires, although the defects had not manifested themselves. Among plaintiffs' claims was that "Defendants withheld information about safety risks concerning the [tires] which, if known, would have caused consumers not to buy or lease, or to pay substantially less for, the [tires] or vehicles equipped with the [tires]." *Id.*at 1089. The court dismissed the RICO claims, finding the plaintiffs "have not suffered cognizable RICO injury by virtue of their purchases of the [tires or cars], absent particularized allegations of the inferior performance of those products." *Id.* at 1092; *see also Maio*, 221 F.3d at 483, 487–88 (affirming dismissal of RICO claims where plaintiffs allegedly paid too much for health insurance but failed to allege they "suffered negative medical consequences resulting from" Aetna's policies).

Similarly, Plaintiffs' "informed choice" theory fails to allege a definite or measureable loss to business or property because Plaintiffs do not allege that the drugs they purchased were defective, and thus fail to allege a concrete injury *stemming from* their purchases.

C. IN THE ABSENCE OF A RICO CLAIM, THE CONSPIRACY CLAIM ALSO FAILS.

The Section 1962(d) claim also fails (Count II). *See Circiello*, 612 F. Supp. 2d at 115–16 ("Without a sufficiently pled RICO claim there can be no RICO conspiracy.").

D. THE STATE LAW CLAIMS FAIL

The state law claims also fail as neither Plaintiff sufficiently alleges injury or causation.[36]

1. Plaintiff LoConte Fails to State a Claim Under Chapter 93A (Count III)

To state a Chapter 93A claim, Plaintiff must allege an economic injury and a "causal connection" between the injury and a statutory violation.[37] *Herman v. Admit One Ticket Agency LLC*, 912 N.E.2d 450, 454 (Mass. 2009); *see also* Mass. Gen. Laws Ch. 93A, §§ 9(1); 2(a).

Plaintiff's alleged injury—denial of "the opportunity to make fully informed decisions," Compl. ¶ 297—is not an "economic injury" sufficient to plead a claim under Chapter 93A. The First Circuit has rejected nearly identical claims in the pharmaceutical context, holding that merely identifying a violation of some "abstract right," such as "the right not to be subject to a deceptive act that . . . cause[d] no economic harm," is not a cognizable loss under Chapter 93A. *Rule v. Fort Dodge Animal Health, Inc.*, 607 F.3d 250, 253–55 (1st Cir. 2010) (affirming dismissal where plaintiff purchased and received benefit of drug but did not allege she suffered purported risks); s*ee also Sergeants Benevolent Ass'n Health & Welfare Fund v. Sanofi-Aventis U.S.*, No. 08–CV–179 (SLT) (RER), 2014 WL 1894303, at *30 (E.D.N.Y. May 12, 2014) (finding no compensable injury under Chapter 93A even assuming doctors would not have prescribed, and plaintiffs would not have purchased, drug absent alleged misrepresentations).

Plaintiff also has not alleged a causal connection between her purported "injury" and Forest's alleged acts. She does not identify any specific misrepresentation that either she or her

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[36] To the extent Plaintiffs' state law claims are premised on the drugs' FDA-approved labels and marketing consistent with those labels, Forest's conduct was affirmatively permitted by state and/or federal regulations, including those of the FDA, and therefore exempted from liability under Massachusetts and Washington law. Mass. Gen. L. ch. 93A, § 3; Wash. Rev. Code § 19.86.170; *see also Bierig v. Everett Sq. Plaza Assocs.*, 611 N.E.2d 720, 728 (Mass. App. Ct. 1993); *Denton v. Dep't Stores Nat'l Bank*, No. C10-5830RBL, 2011 WL 3298890, at *4 (W.D. Wash. 2011).

[37] Elements of a Chapter 93A claim are that plaintiff: (*i*) suffered an injury (*ii*) caused by (*iii*) an unfair or deceptive act or practice. *See Tyler v. Michaels Stores, Inc.*, 984 N.E.2d 737, 744 (Mass. 2013).

physician was exposed to, instead simply asserting, "upon information and belief," that her son's unnamed physician was misled into prescribing Lexapro.[38] Compl. ¶ 201. Such threadbare allegations fail completely under Rule 9(b) and fail to plead a causal connection under Chapter 93A. *See Gorbey ex rel. Maddox v. Am. J. of Obstetrics & Gynecology*, 849 F. Supp. 2d 162, 165 (D. Mass. 2012) (Gorton, J.), *aff'd sub nom. Maddox*, 732 F.3d at 77 (dismissing claims absent facts permitting reasonable inference of causal connection).

2. Plaintiff Kiossovski Fails to State a Claim Under the WCPA (Count IV)

To state a claim under the WCPA, Plaintiff must allege "an injury to [her] business or property" and "causation."[39] *Hangman Ridge Training Stables, Inc. v. Safeco Title Ins. Co.*, 719 P.2d 531, 533 (Wash. 1986); Wash. Rev. Code § 19.86.010 *et seq.*

Plaintiff's theory of injury is payment for Celexa without adequate information about its "likelihood of efficacy." *See, e.g.*, Compl. ¶ 273. Mere payment for a product while being deprived of information is not a cognizable injury under Washington law. At a minimum, a plaintiff must allege that she did not receive the benefit of her bargain. *See Ackley v. Sec. Life Ins. Co. of Am.*, No. C13–432–RSM, 2014 WL 3767459, at *5–6 (W.D. Wash. July 31, 2014) (dismissing claim where plaintiff "fail[ed] to identify an actual and particularized injury suffered"); *Ukpoma v. U.S. Bank. Nat'l Ass'n*, No. 12–CV–0184–TOR, 2013 WL 1934172, at *5 (E.D. Wash. May 9, 2013) (finding no claim where plaintiff lacked information but suffered "no actual injury" to business or property); *Brotherson v. Prof'l Basketball Club, L.L.C.*, 604 F.

[38] Plaintiff cannot rely on "information and belief" pleading to state a cause of action where the information is not in the exclusive control of Defendant. *See, e.g., In re Darvocet, Darvon, & Propoxyphene Prod. Liab. Litig.*, 756 F.3d 917, 931–32 (6th Cir. 2014) (finding "information and belief" pleading insufficient in pharmaceutical case); *Mills v. Bristol-Myers Squibb Co.*, No. CV 11–00968–PHX–FJM, 2011 WL 4708850, at *2–3 (D. Ariz. Oct. 7, 2011) (dismissing claims where plaintiff alleged "on information and belief" that doctor would not have prescribed drug had he known of allegedly omitted facts).

[39] The elements of a WCPA claim are: (*i*) an unfair or deceptive act or practice; (*ii*) occurring in trade or commerce; (*iii*) public interest impact; (*iv*) injury to plaintiff's business or property; and (*v*) causation. *Hangman Ridge Training Stables, Inc. v. Safeco Title Ins. Co.*, 719 P.2d 531, 533 (Wash. 1986).

Supp. 2d 1276, 1295–96 (W.D. Wash. 2009) (finding no injury to business or property where plaintiffs "took advantage of" benefits of purchase). Here, Plaintiff never alleges she did not receive the benefit of her bargain. She paid for and received Celexa, but does not seek to recover on the basis that it failed to perform in her case.

Plaintiff also does not plausibly allege that "but for [Forest's] unfair or deceptive practice, [she] would not have suffered an injury." *Indoor Billboard/Washington, Inc. v. Integra*, 170 P.3d 10, 22 (Wash. 2007). Although she makes conclusory allegations that "absent the fraud and deception, [her payments] would never have occurred," Compl. ¶ 214, her allegations are implausible given the admission that she "relied on her daughter's treating physicians to make informed decisions about which drugs to prescribe her daughter," *id*. ¶ 216, and fails to identify with particularity a single misrepresentation made to her or her daughter's physician.[40] *Green v. Wachovia Mortg. FSB*, No. CV–11–3047-RMP, 2012 U.S. Dist. LEXIS 47772, at *7 (E.D. Wash. Mar. 22, 2012) (dismissing claim for failure to plead misrepresentations with particularity); *Good v. Fifth Third Bank*, No. 2:13–cv–02330–RSM, 2014 WL 2863022, at *3 (W.D. Wash. June 23, 2014) (dismissing claim lacking allegations of but for causation).

3. <u>The Unjust Enrichment Claims Fail (Count V)</u>

Finally, Plaintiffs fail to state a claim for unjust enrichment because the Complaint does not allege that Forest received an unjust benefit *at Plaintiffs' expense*.[41] Under Washington law, a plaintiff must demonstrate that the defendant "retain[ed] money or benefits which in justice and equity belong to another." *Davis v. Homecomings Fin.*, No. 05–1466, 2006 WL 2927701, at *4–5 (W.D. Wash. Oct. 10, 2006) (dismissing claim where defendant merely charged plaintiff a fee for service rendered). Similarly, a Massachusetts plaintiff must show the defendant was enriched

[40] Plaintiff also inappropriately relies on "information and belief" pleading in making conclusory allegations about the essential elements of her fraud claims. Compl. ¶ 216.

[41] The laws of Plaintiffs' home states apply to this claim.

without justification. *See, e.g.*, *Stevens v. Thacker*, 550 F. Supp. 2d 161, 165–66 (D. Mass. 2008) (finding no "injustice" where defendant obtained property for below-market consideration in transaction for mutual benefit of both parties).

Because Plaintiffs admittedly purchased and used the drugs, the Complaint fails to plead facts establishing Forest received an "unjust" benefit from Plaintiffs' purchases.[42]

IV. CONCLUSION

For all of the foregoing reasons, Defendants respectfully request that this Court dismiss the Complaint in its entirety and with prejudice pursuant to Fed. R. Civ. P. 12(b)(6) and 9(b).

Dated: December 19, 2014

Respectfully submitted,

/s/ Edwin G. Schallert

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[42] *See, e.g., Indiana/Kentucky/Ohio Reg'l Council of Carpenters Welfare Fund v. Cephalon, Inc.*, 2014 WL 2115498, at *10 (E.D. Pa. May 21, 2014) (dismissing claims absent allegation patients "did not enjoy [drug's] clinical benefits" and rejecting assertion that "payments for a drug that has been promoted off-label, without more," present unjust circumstances); *Seargeants Benevolent*, 2014 WL 1894303, at *34–35 (finding no unjust enrichment absent evidence patients suffered "ill-effects or found [drug] to be ineffective"); *Prohias v. Pfizer*, 490 F. Supp. 2d 1228, 1236 (S.D. Fla. 2007) (dismissing unjust enrichment claim where plaintiff "received the benefit from taking [drug]" and later claimed he "would not have purchased [it] but for the misleading advertisements").

CERTIFICATE OF SERVICE

I, J. Robert Abraham, hereby certify that this document, filed through the ECF system, will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF) and paper copies will be sent to those attorneys still active indicated as non-registered participants on December 19, 2014.

/s/ J. Robert Abraham

J. Robert Abraham